



Office of Pharmacy Affairs
340B Database

OPA Database Guide For Public Users – Recertification



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Covered Entities Guide for Public Users

Recertifying a Covered Entity

The Office of Pharmacy Affairs (OPA) is required to recertify all participating 340B covered entities annually to ensure 340B database accuracy and promote compliance with 340B program requirements.

Authorizing Official Advance Notification

The Authorizing Official (AO) and Primary Contact (PC) receive the advanced notification email from HRSA OPA that recertification of their covered entity and the recertification period to include a start and end date. The advanced notification email notifies the AO and PC of the forthcoming requirement. User Name and Password will be distributed solely to the listed AO on the official recertification start date. The user name is also the batch name.

The user name and password email contain the following:

- A link to the 340B database
- Login instructions
- Instructions for completing the online recertification process (recertification user guide)
- Date the recertification is to be completed.

Note: An AO who has more than one parent covered entity will receive more than one recertification notification, each with a different user name and password. A parent hospital with associated outpatient facilities will only receive one user name and password for all covered entities/child sites.

The parent entity must be recertified first. For hospitals, the **Qualification Information** tab (QI) will auto populate all child sites after the parent has recertified.

When OPA has completed verification, the user name and password used to log in for an entity will no longer be active.

For batches with multiple covered entities, repeat the following steps for each entity, as the AO will receive a separate email containing the user name and password for each one. You must log out after each session before logging in to recertifying another entity.

Logging into Recertification

When you receive the follow-up recertification email from OPA, follow these login instructions:

- 1) Click the URL link in the email.
- 2) When the **Welcome to OPA** login page displays, copy the user name and password from email and paste them into the user name and password fields on the login page, ensuring that there are no spaces before or after the user name or password.

The username, password and link to your covered entity records shown below will provide you with access to your entities' data as it currently exists in the 340B Program database. Please log into the database to review, revise (if necessary) and certify entities and their associated contract pharmacies that are still participating in the 340B Program. Decertify any entities that are no longer participating in the 340B Program. After all of your entities have been reviewed, you will electronically sign and submit your certified entities and/or decertified entities.

Please note that any changes made to your entity details must be reviewed and approved by HRSA. You will receive the '340B Recertification Complete' e-mail at that time and may verify the changes through the 340B database's public search function.

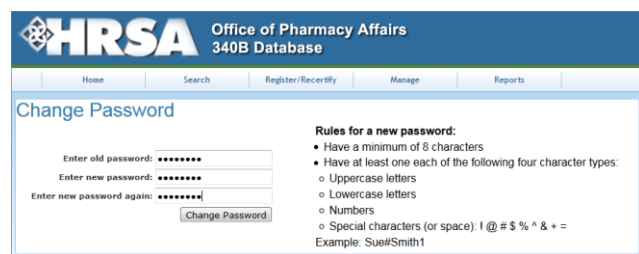
Site: http://96.127.55.1/OPA_OA/RecertBatchDashboard.aspx?BATCH_ID=89481

Username: TB01199
Password: t!6XAz@5

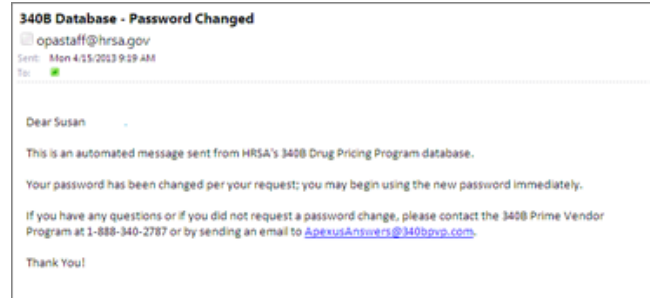
Note: Requesting that your login information be re-sent will result in assignment of a new, temporary password.



- 3) Paste the authentication information into the **User Name** and **Password** fields.
- 4) Click the **Sign In** button. When the U.S. government warning pop-up window displays, click **OK**.
- 5) The **340B Database – Password Change** page requires changing your temporary password.
- 6) Enter a new password twice that meets the password requirements listed on the page.
- 7) Click the **Change Password** button.



After the password is successfully changed, an email acknowledgement is sent to the AO that the password has been updated. The log on credentials will be valid until the entity is recertified by OPA.



Recertification Batch Dashboard

The **Batch Dashboard** page displays the covered entity that will be recertified. The number of the batch you are logged into is displayed at the right side of the header bar.

Recertification Dashboard > Initiative Dashboard > Batch Dashboard

Recertification Initiative Name:	CG RGT 04202015	Entity Type:	Consolidated Health Center Program
Batch Name:	CH0622450	End Date:	7/1/2015
Start Date:	4/20/2015	PM/AO Name:	ELIZABETH TREVINO
Certification Due Date:	4/21/2015	PM/AO Phone:	817-546-6478
PM/AO Email:	ENTITY- AuthorizingOfficialEmail@futrend.com		

Covered Entities

The number of rows returned: 3 Rows/Page: 200

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	Status
CH0622450	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	North Texas Area Community Health Centers, Inc.	2100 N Main St	Fort Worth	TX	76164	Incomplete
CH062245A	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	NORTHSIDE COMMUNITY HEALTH CENTER	2106 N Main St	Fort Worth	TX	76164	Incomplete
CH062245B	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	Southeast Community Health Center	3212 Miller Ave.	Fort Worth	TX	76119	Incomplete

Note: Entities will be batched according to their parent/child relationships. Entities that do not have a parent/child relationship will be batched separately (one entity per batch).

- 8) Click the entity's **340B ID** link.

Covered Entity Details

- 9) The **Covered Entity Details** section displays read-only data from the entity's 340B database record.

Note: The **Nature of Support** funding check boxes only appear for TB and STD entities.

Covered Entity Details Edit

340B ID: TB01199

Entity Name: BAYSTATE MEDICAL CENTER
Entity Sub-Division Name: HIGH STREET HEALTH CENTER,
WESSON MEMORIAL HOSPITAL UNIT
Medicare Provider Number:

Entity Type: Tuberculosis
Employer Identification Number:
Grant Number: TB-MA

Nature of Support:

☐ Direct Funding (dollars received from CDC or an intermediate organization)

☐ In-Kind products or services (see note below; must have been purchased with section 317 funds)

☐ None

Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

To modify data in this section, click the [Edit](#) link. The **Sub-Division Name**, **EIN** (*hospitals only*), and **Grant Number** (and **Nature of Support** checkboxes for TB and STD entities) become editable. When finished, click [Continue](#) to save your changes or [Undo](#) to cancel them.

Covered Entity Details Continue Undo

***340B ID:** TB01199

***Entity Name:** BAYSTATE MEDICAL CENTER

Entity Sub-Division Name: HIGH STREET HEALTH CENTER, WESSON MEMORIAL HOSPITAL UNIT

Entity Type: Tuberculosis

***Employer Identification Number:** (Enter the registrant's EIN if a sub-grantee/sub-recipient)

Grant Number: TB-MA (if known/applicable)

Medicare Provider Number: (only required for hospital entity types)

*** Nature of Support:**

☐ Direct Funding (dollars received from CDC or an intermediate organization)

☐ In-Kind products or services (see note below; must have been purchased with section 317 funds)

☐ None

Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

Covered Entity Address

- 10) The **Covered Entity Address** section displays read-only data from the entity's 340B database record. If you click **Edit** in the **Covered Entity Address** section, all address fields become editable.

Covered Entity Address

Street Address (PO Box Not Allowed)

140 HIGH STREET
SPRINGFIELD, MA 01105

☐ Billing Address Same as Street Address

Billing Address

MDPH / TB CONTROL
STATE LAB
305 SOUTH STREET
JAMAICA PLAIN, MA 02130

☐ Shipping Address Same as Street Address

Shipping Address (PO Box Not Allowed)

Shipping Address 1

BAYSTATE MEDICAL CENTER
140 HIGH STREET
SPRINGFIELD, MA 01105

To modify data in this section, click the [Edit](#) link. All address fields become editable.

Covered Entity Address

Street Address (PO Box Not Allowed)

Continue Undo

*Address Line 1:

140 HIGH STREET

Address Line 2:

*City:

SPRINGFIELD

*State:

Massachusetts

*Zip:

01105

-

☐Billing Address Same as Street Address

Billing Address

Continue Undo

*Organization Name:

MDPH / TB CONTROL

*Address Line 1:

STATE LAB

Address Line 2:

305 SOUTH STREET

*City:

JAMAICA PLAIN

*State:

Massachusetts

*Zip:

02130

-

☐Shipping Address Same as Street Address

Shipping Address (PO Box Not Allowed)

Add

New Shipping Address

Continue Undo

*Organization Name:

*Address Line 1:

Address Line 2:

*City:

*State:

Select a State

*Zip:

-

Shipping Address 1

Edit Delete

BAYSTATE MEDICAL CENTER
140 HIGH STREET
SPRINGFIELD, MA 01105

- If the **Billing Address Same as Street Address** box is unchecked, the billing address fields allow you to edit the existing billing address or add a new one.
- If the **Shipping Address Same as Street Address** box is unchecked, an **Add** link appears to allow you to add one or more shipping addresses or edit or delete an existing shipping address. All address changes will be reviewed by OPA for consistency with shipping address requirements. **No PO boxes** can be listed except for billing addresses.

When changes to an address are complete, click **Continue** to save them or **Undo** to cancel them.

Covered Entity Date Information

- 11) The **Covered Entity Date Information** section allows you to terminate an entity or edit the termination reason, dates, and comments.

Covered Entity Date Information Edit

Registration Date: 7/1/2003 Participating Start Date: 7/1/2003

Participating Approval Date: 11/18/2004 Termination Reason:

Termination Date:

The date the entity became ineligible:

Last date that 340B drugs were or will be purchased under this 340B ID:

Termination Comments:

To modify data in this section, click the **Edit** link. The termination fields become editable.

Covered Entity Date Information Continue Undo

Registration Date: 7/1/2003

☐ Participating Approval Date: 11/18/2004

Participating Start Date: 7/1/2003

Termination Reason: site closure
If none of these reasons apply, stop here and e-mail 340b.recertification@hrsa.gov for additional guidance.

Termination Date: 4/1/2015

* The date the entity became ineligible:

* Last date that 340B drugs were or will be purchased under this 340B ID:

Termination Comments: Please provide a brief description of the facts surrounding the reason for termination and how the effective date was determined. This information, including relevant dates, may be made available to manufacturers and the public. If 340B drugs were purchased after losing eligibility, HRSA urges working with affected manufacturers regarding possible repayment.

- **Termination Reason:** Select the reason from the drop-down list.
- **Termination Date** – Automatically populated as first day of the following quarter when a Termination Reason is selected (not editable).
- **Date Entity Became Ineligible:** Enter the date when the entity became ineligible for participation in the 340B Program.

Select a Termination Reason
DSH percentage below statutory minimum
for-profit conversion
loss of qualifying grant/support
site closure

- **Last Date Drugs Were/Will Be Purchased:** Enter the last date when drugs were or will be purchased under the entity's 340B ID.
- **Termination Comments:** Enter any additional comments about the termination.

When changes are completed, click **Continue** to save them or **Undo** to cancel them.

Qualification Information (Hospitals Only)

The **Qualification Information (QI)** section only applies to hospitals. It contains required fields that must be completed before continuing with recertification. The fields that display in this section vary depending on the entity's hospital type:

- Children's (PED)
- Critical Access (CAH),
- Disproportionate Share (DSH),
- Free Standing Cancer (CAN)
- Rural Referral Center (RRC)
- Sole Community (SCH)

Data recorded in the QI section for the parent hospital is updated to all its child outpatient facilities when the parent is certified.

Fields in the **Qualification Information** section display as blank. They require the Authorizing Official to enter information. If the information entered does not pass validation, the system requires the authorizing official to "decertify" the CE. Decertifying the parent automatically decertifies all associated children.

Qualification Information

Edit

Qualifying information for outpatient facilities (child sites) will be automatically carried over from the main hospital record; please email us at 340B.recertification@hrsa.gov if you need to report an independent DSH adjustment percentage, cost reporting period or ownership classification for a particular site. Organizations with DSH percentages below applicable thresholds must decertify the parent hospital and ALL associated outpatient facilities.

☒ Entity is a Children's Hospital defined by section 1886(d)(1)(B)(iii) of the Social Security Act, and this status is recognized by CMS.

Disproportionate Share Adjustment Percentage:

Cost Reporting Period From: to

Calculation Date:

Calculation Based On: Medicare Cost Report Data

Hospital Classification: Private, Non-Profit Hospital with State/Local Govt Contract

12) Click the **Edit** link to make changes to the **Qualification Information** fields.

Qualification Information

Continue Undo

From the hospital's most recently filed Medicare Cost Report, update the following:

* ☒ Entity is a Children's Hospital defined by section 1886(d)(1)(B)(iii) of the Social Security Act, and this status is recognized by CMS.

* Disproportionate Share Adjustment Percentage: 34 % (i.e., 25.75%)

* Cost Reporting Period
From: 1/1/2013 to 12/31/2013

* Calculation Date: 3/1/2011

* Calculation Based On: Medicare Cost Report Data

* Hospital Classification: Owned or Operated by State or Local Government

You have chosen to change your listed hospital classification. Please contact 340B.recertification@hrsa.gov to determine the documentation necessary to update your covered entity profile within 5 business days.

Note: **Continue** and **Undo** links appear in the upper right corner of this section. Click **Continue** to advance to the next section or **Undo** to clear your edits.

- 13) Check the box if the hospital qualifies as the specified registered entity type as defined by section CFR of the Social Security Act, and this status is recognized by CMS.
- 14) **Disproportionate Share Adjustment Percentage:** (PED, DSH, CAN, RRC, SCH only) – Enter the applicable percentage between 0 and 100 for the disproportionate share adjustment. This percentage must equal or exceed a minimum percent based on the hospital entity type. A lesser percent will prompt an error message that will prevent recertification from continuing. For most hospitals this can be found on Worksheet E, part A, line 33. PED and CAN hospitals use a calculation on the S-3 or via an independent auditor.
- 15) **Cost Reporting Period:** (PED, CAH, DSH, CAN, RRC, and SCH only) – Enter a date range manually in mm/dd/yyyy format or by clicking the calendar icon and selecting the **From:**___ and **To:**___ dates. The **“To:”** date field must be a valid date no more than 17 months in the past (may not be a future date).
- 16) **Calculation Date:** This date applies only to PED and CAN hospitals.
- 17) **Calculation Based On:** Only applies to PED and CAN hospitals. Click the drop-down list to select

Select One

Select One
 Official Determination from HHS Contractor
Medicare Cost Report Data
 Independent Auditor
- 18) **Hospital Classification:** a hospital classification.

Select One

Owned or Operated by State or Local Government
 Private, Non-Profit Hospital with State/Local Govt Contract
Public or Private Non-Profit Hospital Granted Governmental Powers

If you select a different classification than what is recorded for the entity, the system displays the message: “You have chosen to change your listed hospital classification.”

Please contact 340B.recertification@hrsa.gov to determine the documentation necessary to update your covered entity profile within 5 business days.”

Note: An email window opens for the authorizing official to notify OPA within five business days of the change in classification. Changing a covered entity’s ownership status is considered a material change reviewable by HRSA OPA to determine if there was a loss of eligibility based upon this change.

If parent entity's eligibility for the 340B program has changed, the authorizing official must be decertified. This will cause associated hospital children to be automatically decertified. Children of non-hospitals can remain active.

All change requests are blocked from submission until a covered entity recertification is complete and reviewed by OPA. A covered entity will not be able to submit an electronic change request during this period, but a manual change request for updating and Authorizing Official may be submitted to retrieve a user name and password. Click **Forms** in the **Useful Links** on the homepage to retrieve the manual change request form and submit to HRSA OPA staff inbox, as stated on the form. If the authorizing official contact information changes, recertification confirmations will be emailed to the new authorizing official's email addresses.

Medicaid Billing/Orphan Drug Exclusion

- 19) The **Medicaid Billing** section identifies whether or not the entity will bill Medicaid for drugs purchased at 340B drug prices.

Medicaid BillingEdit

Medicaid Billing Information

You must answer the following question regarding Medicaid Billing:

Will you bill Medicaid for drugs purchased at 340B drug price? ☒ Yes ☐ No

Medicaid Number(s):

Medicaid Number	State
-----------------	-------

NPI Number(s):

NPI Number
1184655417

Orphan Drug Exclusion

340B hospitals subject to the orphan drug exclusion (i.e., critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act. Please choose one of the following:

☒ The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.

☐ The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drugs exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.

Note: Any change to your selection will be effective on the first day of the quarter following approval by OPA.

To modify data in this section page, click the **Edit** link.

Medicaid Billing

Continue Undo

Medicaid Billing Information

You must answer the following question regarding Medicaid Billing:

Will you bill Medicaid for drugs purchased at 340B drug price? ☒ Yes ☐ No

Medicaid Exclusion Tutorial

Medicaid Number(s):

Add

Medicaid Number	State	
<input type="text"/>	Select a State	Insert Cancel

NPI Number(s):

Add

NPI Number		
1184055417	Edit	Delete

Orphan Drug Exclusion

340B hospitals subject to the orphan drug exclusion (i.e., critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act. Please choose one of the following:

☒ The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.

☐ The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drugs exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.

Note: Any change to your selection will be effective on the first day of the quarter following approval by OPA.

If the answer to the ***“Will you bill Medicaid for drugs purchased at 340B drug price?”*** question is **Yes**, at least one Medicaid Number and/or NPI Number must be furnished. Clicking an **Add** link allows you to add one or more Medicaid Number and/or NPI Number or edit or delete an existing Medicaid Number and/or NPI Number.

A covered entity may opt out by selecting **No**, removing all Medicaid/NPI numbers.

The ***Orphan Drug Exclusion*** section applies only to critical access hospitals (CAH), free-standing cancer hospitals (CAN), sole community hospitals (SCH), and rural referral centers (RRC) to specify whether the hospital will purchase orphan drugs under the 340B program and maintain auditable records to show compliance, or whether the hospital will purchase orphan drugs outside the 340B program and will not be required to maintain auditable records regarding orphan drugs purchased. CAN hospitals cannot use a GPO to purchase orphan drugs for a non-orphan indication. The other three hospital types may use a GPO if desired.

Note: Any changes made in this section will not be effective until the first day of the following quarter.

When changes are completed, click **Continue** to save them or **Undo** to cancel them.

Contact Information

- 20) The **Contact Information** section will appear next if you are a grantee/non-hospital covered entity. You have the ability to edit this section. If a hospital, also review the QI fields described later in the user guide.

Contact Information

Authorizing Official Edit

Name: Jennifer Cochran
Title: Director, Division of Tuberculosis Prevention
Phone: 617-983-6596 **Ext:**
Email: Jennifer.Cochran@state.ma.us

☐ Make Primary Contact Information same as Authorizing Official

Primary Contact

Name: Sally Cheney
Title: Director, Policy & TB Clinic Services
Phone: 617-983-6553 **Ext:**
Email: sally.cheney@state.ma.us

Update Terminate Cancel

To modify data in this section page, click the [Edit](#) link.

Contact Information

Authorizing Official Continue Undo

***Name:** Jennifer Cochran
***Title:** Director, Division of Tuberculosis P
*** Phone:** 617-983-6596 **Ext:**
(xxx-xxx-xxxx)
***Email:** Jennifer.Cochran@state.ma.us

☐ Make Primary Contact Information same as Authorizing Official

Primary Contact Continue Undo

***Name:** Sally Cheney
***Title:** Director, Policy & TB Clinic Service
*** Phone:** 617-983-6553 **Ext:**
(xxx-xxx-xxxx)
***Email:** sally.cheney@state.ma.us

The primary contact should be someone employed by the Covered Entity

Update Terminate Cancel

For either the AO or the Primary Contact information, when changes are completed, click [Continue](#) to save them or [Undo](#) to cancel them.

- 21) Click the Update button to complete certification of the entity. You will be asked if you are satisfied with the information for the entity. Click **OK** if you are satisfied with your edits. You will be unable to request additional changes until OPA review is complete.

Are you satisfied with the information on file for this site? After continuing, you will be unable to request additional changes until OPA review is complete.

OK Cancel

- 22) You are returned to the **Batch Dashboard**. The entity you just certified is moved to the bottom of the list in the **Covered Entities** table with a status of "Certified"

[Recertification Dashboard](#) > [Initiative Dashboard](#) > [Batch Dashboard](#)

Recertification Initiative Name: CG RGT 04202015

Batch Name: CH0622450

Start Date: 4/20/2015

Certification Due Date: 4/21/2015

PM/AO Name: ELIZABETH TREVINO

PM/AO Email: ENTITY-
AuthorizingOfficialEmail@futrend.com

Entity Type: Consolidated Health Center Program

End Date: 7/1/2015

PM/AO Phone: 817-548-6478

Covered Entities

The number of rows returned: 3 Rows/Page: 200

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	Status
CH062245A	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	NORTHSIDE COMMUNITY HEALTH CENTER	2108 N Main St	Fort Worth	TX	76164	Incomplete
CH062245B	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	Southeast Community Health Center	3212 Miller Ave.	Fort Worth	TX	76119	Incomplete
CH0622450	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	North Texas Area Community Health Centers, Inc.	2100 N Main St	Fort Worth	TX	76164	Certified

1

Attest and Recertify

The **Authorized Signature** section is the final step after the parent and all child sites have been reviewed and updated.

**Consolidated Health Center Program Grantee/ Program
Manager Batch Certification 2015**

NOTE: Recertification is not complete until you check the certification statement below and click the "Attest and Recertify" button.

Covered Entities

The number of rows returned: 3 Rows/Page:

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	Status
CH0622450	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	North Texas Area Community Health Centers, Inc.	2100 N Main St	Fort Worth	TX	76164	Certified
CH062245A	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	NORTHSIDE COMMUNITY HEALTH CENTER	2106 N Main St	Fort Worth	TX	76164	Certified
CH062245B	CH0622450	NORTH TEXAS AREA COMMUNITY HEALTH CENTERS INC	Southeast Community Health Center	3212 Miller Ave.	Fort Worth	TX	76119	Certified

1

Program Manager/Authorizing Official

Name: ELIZABETH TREVINO
Title: CEO
Phone: 817-546-8478 **Ext:**
Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Authorized Signature

☒ The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. Failure to recertify may be grounds for removal from the 340B Program.

The undersigned further acknowledges the 340B covered entity's responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:

- (1) all information listed on the 340B Program database for the covered entity is complete, accurate, and correct;
- (2) the covered entity meets all 340B Program eligibility requirements, including (if applicable) section 340B(a)(4)(L)(iii) and the Statutory Prohibition on Group Purchasing Organization Participation Policy Release 2013-1, which ensures that the covered entity hospital does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement;
- (3) the covered entity will comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, and the exclusion of orphan drugs for critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers;
- (4) the covered entity maintains auditable records demonstrating compliance with the requirements described above;
- (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described above;
- (6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
- (7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
- (8) the covered entity acknowledges that if there is a breach of the requirements described above that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

Attest and Recertify

- 23) Check the box to attest that you have read and understand that you are authorized to sign for the entity and attest to the entities compliance within the 340B requirements providing that the information listed is complete and accurate.
- 24) Click the **Attest and Recertify** button. The recertification process now complete and the covered entities record will be sent to HRSA OPA for review. HRSA OPA has the right to accept, reject, or accept partial updates to a covered entity's record as requested by the AO. Once this step is complete, the AO will receive email confirmation that recertification is complete.

Thank you for recertifying your 340B Covered Entity records. If you are the authorizing official for more than one organization, you will need to repeat the verification process for each additional organization. Otherwise, no further action is required on your part at this time.

The information you provide during recertification will be reviewed by OPA for completeness and compliance with program requirements. Any changes you submit, if approved, will not be reflected in the 340B database until you receive an e-mail informing you that recertification is complete. At that time, you may review your information at this link:

<http://opanet.hrsa.gov/OPA/CESearch.aspx>

Need help or have additional questions? Please contact the 340B Recertification Team:

Apexus Phone: 1-888-340-2787
Email: ApexusAnswers@340bpvp.com

- 20) Click the button. You will be returned to the OPA home page for AOs.
- 25) Repeat the certification steps above until all covered entities in the batch have been recertified. When the last covered entity in the batch is certified, the system will display the **Attest and Certify** page.

Note: For multiple non-hospitals that are batched separately, you must log out after each session and log back in again to recertify another entity. Repeat the steps above for each entity.

Decertifying a Covered Entity

An Authorizing Official can request to “decertify” a covered entity, which is requesting that the entity will no longer participate in the 340B Program. If the Authorizing Official decertifies the parent hospital, associated children are automatically decertified. However, the Authorizing Official can choose to certify the parent hospital while selectively decertifying certain children.

Follow these steps to decertify an entity:

- 1) Log in using the user ID and password from the follow-up recertification email from OPA.

The **Batch Dashboard** page for the initiative displays.

[Recertification Dashboard](#) > [Initiative Dashboard](#) > [Batch Dashboard](#)

Recertification Initiative Name: DW UI Report 12/27/2014

Batch Name: UI7893A

Start Date: 11/24/2014

Certification Due Date: 11/25/2014

PM/AO Name: Linda Cowan

PM/AO Email: ENTITY-AuthorizingOfficialEmail@futrend.com

Entity Type: Urban Indian

End Date: 11/25/2014

PM/AO Phone: 928-526-2968

Covered Entities

The number of rows returned: 1 Rows/Page: 200

340B ID	Batch Name	Entity Name	Subdivision Name	Address	City	State	Zip	Status
UI7893A	UI7893A	NATIVE AMERICANS FOR COMMUNITY ACTION INC	FAMILY HEALTH CENTER	1500 EAST CEDAR AVE., STE 26	FLAGSTAFF	AZ	86004	Incomplete

1

- 2) Click the link in the **340B ID** column

The **Covered Entity Details** page displays.

Medicaid Billing [Edit](#)

Medicaid Billing Information

You must answer the following question regarding Medicaid Billing:

Will you bill Medicaid for drugs purchased at 340B drug price? ☐ Yes ☒ No

Contact Information [Edit](#)

Authorizing Official

Name: Linda Cowan
Title: Chief Executive Officer
Phone: 928-526-2968 **Ext:**
Email: ENTITY-AuthorizingOfficialEmail@futrend.com

☐ Make Primary Contact Information same as Authorizing Official

Primary Contact

Name: Debra Laughlin
Title: Clinic Nurse
Phone: 928-773-1245 **Ext:** 20
Email: ENTITY-Contact_Email@futrend.com

- 3) Scroll to the bottom of the page and click the [Terminate](#) button.

The **Covered Entity Details** page displays validation errors for any required fields are missing information.

Errors:
• Please enter Employee Identification Number.

Covered Entity Details

***340B ID:** UI7893A Continue Undo

***Entity Name:** NATIVE AMERICANS FOR COMMUNITY ACTION INC

Entity Sub-Division Name: FAMILY HEALTH CENTER

Entity Type: Urban Indian

***Employer Identification Number:** (Enter the registrant's EIN if a sub-grantee/sub-recipient) *

Grant Number: (if known/applicable)

Medicare Provider Number: (only required for hospital entity types)

4) Fix any validation errors and click the **Continue** link to apply your changes.

5) Click the **Terminate** button again.

The **Covered Entity Details** page prompts for any missing termination information information.

Errors:
• Termination Reason is required.
• Termination Date is required.
• The date the entity became ineligible is required.
• Last date that 340B drugs were or will be purchased under this 340B ID is required.

Covered Entity Details

340B ID: UI7893A

Entity Name: NATIVE AMERICANS FOR COMMUNITY ACTION INC

Entity Sub-Division Name: FAMILY HEALTH CENTER

Medicare Provider Number:

Entity Type: Urban Indian

Employer Identification Number: 11-1111111

Grant Number:

Covered Entity Address

Street Address (PO Box Not Allowed)
1500 EAST CEDAR AVE.
STE 26
FLAGSTAFF, AZ 86004

☒ Billing Address Same as Street Address

☒ Shipping Address Same as Street Address

Covered Entity Date Information Continue Undo

Registration Date: 12/4/2007

☐ **Participating Approval Date:** 6/20/2012

Participating Start Date: 7/1/2012

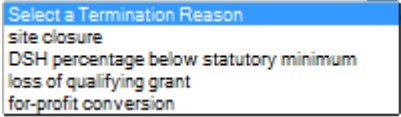
Termination Reason: site closure
If none of these reasons apply, stop here and e-mail 340b.recertification@hrsa.gov for additional guidance.

Termination Date: 11/24/2014

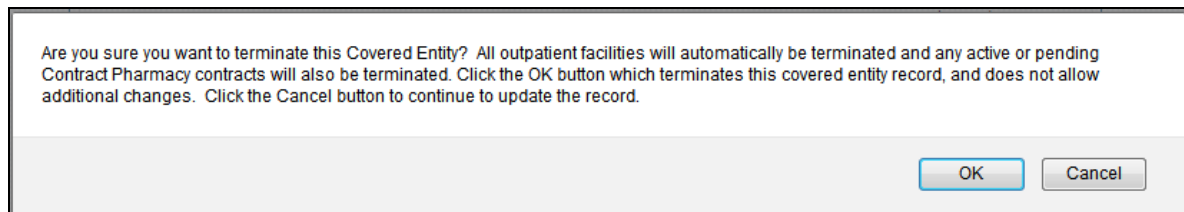
The date the entity became ineligible: 11/24/2014

Last date that 340B drugs were or will be purchased under this 340B ID: 11/15/2014

Termination Comments:
Upon completion of this termination request, your Authorizing Official will receive an email. Please ensure that your AO reviews the email and responds to the content.

- 6) **Termination Reason:** Select the reason the entity is being decertified. If none of these reasons apply, send an email to: 340B.recertification@hrsa.gov .

- 7) **Termination Date:** Enter the effective termination date manually in mm/dd/yyyy format or using the calendar icon.
- 8) **Date the entity became ineligible:** Enter in mm/dd/yyyy format or select with the calendar icon the effective date the entity is ineligible for the 340B program.
- 9) **Last date that 340B drugs were purchased:** Enter the last date drugs were purchased at 340B prices.
- 10) **Termination Comments:** Briefly describe the reason for termination and how the effective date was determined. Information entered in this section may be made available to manufacturers and the public. If 340B drugs were purchased after the entity became ineligible, affected manufacturers may be entitled to repayment.
- 11) When finished, click the **Terminate** button again.

A screen message displays a warning that if you decertify the entity, all outpatient facilities will also be decertified. If terminating any covered entity parent or child, the request will notify that there will be a termination of all contract pharmacies also.



- 12) Click the **OK** button. The **Authorize and Submit** screen displays. You will be prompted to attest and recertify.

(Back to [Getting Started for Public Users](#))

Other Covered Entities User Guides

[Searching for a Covered Entity](#)

[Viewing A Covered Entity Record](#)

[Exporting Search Results Data](#)

[Registering a Covered Entity/Outpatient Facility](#)

[Submitting a Change Request](#)